

E-1a

| U.S. DEPARTMENT OF AGRICULTURE<br>FOOD SAFETY AND INSPECTION SERVICE<br>INTERNATIONAL PROGRAMS |                              |        |  | REVIEW DATE<br>8/17/2001 |     | NAME OF FOREIGN LABORATORY<br>National Veterinary and Food Institute (EELA) |     |     |     |                   |  |  |  |  |  |
|--|------------------------------|--------|--|--------------------------|-----|---|-----|-----|-----|-------------------|--|--|--|--|--|
| FOREIGN COUNTRY LABORATORY REVIEW  |                              |        |  |                          |     |   |     |     |     |                   |  |  |  |  |  |
| FOREIGN GOV'T AGENCY<br>National Food Agency   |                              |        | CITY & COUNTRY<br>Helsinki, Finland                            |                          |     | ADDRESS OF LABORATORY<br>P.O. Box 45 (Hämeentie 57)                         |     |     |     |                   |  |  |  |  |  |
| NAME OF REVIEWER<br>Dr. Gary D. Bolstad  |                              |        | NAME OF FOREIGN OFFICIAL<br>Dr. Timo Hirvi, Dr. Anne Fagerlund |                          |     |   |     |     |     |                   |  |  |  |  |  |
| Residue Code/Name  |                              |        | chc  | abc                      | cap | oph   | hvm | des | sul |                   |  |  |  |  |  |
| SAMPLING PROCEDURES  | REVIEW ITEMS                 | ITEM # | EVALUATION CODE  |                          |     |   |     |     |     |                   |  |  |  |  |  |
|  | Sample Handling              | 01     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | Sampling Frequency           | 02     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | Timely Analyses              | 03     |  | A                        | A   | A   | A   | A   | A   | C                 |  |  |  |  |  |
|  | Compositing Procedure        | 04     |  | O                        | O   | O   | O   | O   | O   | O                 |  |  |  |  |  |
|  | Interpret Comp Data          | 05     |  | O                        | O   | O   | O   | O   | O   | O                 |  |  |  |  |  |
|  | Data Reporting               | 06     |  | A                        | A   | A   | A   | A   | A   |                   |  |  |  |  |  |
| ANALYTICAL PROCEDURES  | Acceptable Method            | 07     | EVALUATION CODE  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | Correct Tissue(s)            | 08     |  | A                        | A   | A   | A   | A   | C   | C                 |  |  |  |  |  |
|  | Equipment Operation          | 09     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | Instrument Printouts         | 10     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
| QUALITY ASSURANCE PROCEDURES   | Minimum Detection Levels     | 11     | EVALUATION CODE  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | Recovery Frequency           | 12     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | Percent Recovery             | 13     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | Check Sample Frequency       | 14     |  | A                        | A   | A   | C   | A   | A   | A                 |  |  |  |  |  |
|  | All analyst w/Check Samples  | 15     |  | A                        | A   | A   | C   | A   | A   | A                 |  |  |  |  |  |
|  | Corrective Actions           | 16     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
|  | International Check Samples  | 17     |  | A                        | A   | A   | A   | A   | A   | A                 |  |  |  |  |  |
| REVIEW PROCEDURES  | Corrected Prior Deficiencies | 18     | EVAL. CODE   | O                        | O   | A   | O   | A   | O   | O                 |  |  |  |  |  |
| OTHER REVIEW   |                              | 19     | EVAL. CODE   |                          |     |   |     |     |     |                   |  |  |  |  |  |
|  |                              | 20     | EVAL. CODE   |                          |     |   |     |     |     |                   |  |  |  |  |  |
| SIGNATURE OF REVIEWER<br><i>JD Bolstad</i>   |                              |        |  |                          |     |   |     |     |     | DATE<br>8/17/2001 |  |  |  |  |  |

| <b>FOREIGN COUNTRY LABORATORY REVIEW</b><br><i>(Comment Sheet)</i> |       | REVIEW DATE<br>8/17/2001   | NAME OF FOREIGN LABORATORY<br>National Veterinary and Food Institute (EELA) |
|--|-------|--|---|
| FOREIGN GOV'T AGENCY<br>National Food Agency                       |       | CITY & COUNTRY<br>Helsinki, Finland  | ADDRESS OF LABORATORY<br>P.O. Box 45 (Hämeentie 57)                         |
| NAME OF REVIEWER<br>Dr. Gary D. Bolstad                            |       | NAME OF FOREIGN OFFICIAL<br>Dr. Timo Hirvi, Dr. Anne Fagerlund   |   |
| RESIDUE  | ITEM  | COMMENTS   |   |
| sul  | 03    | Instrument problems caused turnaround times for sulfonamides of up to 2 months earlier in the year, but the problem was rectified and analyses were now completed within 4 weeks.  |   |
| des, sul   | 08    | The following tissue matrices were used: for diethylstilbestrol - urine, feces, and plasma; and for sulfonamides muscle and kidney.  |   |
| op   | 14,15 | No organophosphates had been detected in field samples for the previous ten years, and Finland was phasing out sampling for OPs as part of the national residue testing program. Seventeen field samples were analyzed for OPs in 2000 and 5 in 2001. Positive OP spiked samples were run with each sample set, but no unknown or blank intralaboratory check samples were provided to analysts. |   |
| hvm  | 18    | All heavy metals were now included in the testing program, including arsenic and mercury.  |   |



## Microbiology Laboratory Audit

### General

Name & location of lab: Atria Oyj, Kauhajoki, Finland, August 28, 2001

Private or gov't lab? Private

How & when was accreditation obtained? 12/1/2000, Finnish Center for Metrology and Accreditation (FINAS)

How & how often is accreditation maintained? Annual review; renewal every 4 years

When and how is payment for analysis provided? N/A (only samples from this establishment are analyzed in this laboratory)

Are results released before payment is received? N/A

What are the qualifications of the analyst(s) performing the individual tasks within a method? Thirty years experience in laboratories, courses in microbiology.

What are the qualifications of the direct supervisor of the analyst(s)? Her direct supervisor is also a laboratory technician; that person's supervisor has a PhD in chemistry.

### Methodology for HACCP *Salmonella* samples (regulatory labs)

Does this lab analyze HACCP *Salmonella* samples? Yes

How are HACCP *Salmonella* samples received & recorded? The lab is in the establishment

Are HACCP *Salmonella* samples analyzed on the day of receipt? Yes

What method(s) is used for HACCP *Salmonella* samples? NMKL 71:1992, [modified by] EELA 3432: 1999

Is it a qualitative method (i.e. +/- result)? Yes

Are HACCP ground beef samples analyzed for *Salmonella*? No

What is the size of the ground beef test portion?

What buffer (and what volume) is used for:

Sponge samples for *Salmonella*? 10 ml BPW

Poultry rinsates for *Salmonella*? N/A

*Salmonella* ground beef sample homogenates? N/A

What is the formulation of the Buffered Peptone Water you use?

|                                |          |
|--------------------------------|----------|
| Peptone                        | 10.0 g/l |
| NaCl                           | 5.0 "    |
| Disodium phosphate             | 3.6 "    |
| Potassium dihydrogen phosphate | 1.5 "    |
| Distilled water                | 1000 ml  |
| pH 6.8 ± 0.2 @ 25°C            |          |

What analytical controls are used for *Salmonella* analyses (i.e. control cultures, etc.)? *S. typhimurium*

Are they employed for each sample set? Yes

How are HACCP *Salmonella* results expressed? Detected / not detected

How are HACCP *Salmonella* results recorded?: In a computer program, in chart form

How and to whom are HACCP *Salmonella* results reported? Positive results would be given to the IIC by hand and to establishment

Are "check" samples periodically used to test the proficiency of the lab and analysts for *Salmonella* testing? Yes

1. For individual analysts or for the lab as a whole? Lab as a whole; the analyst participates. Provided by the Swedish National Food Administration, four times annually (but the check samples do not always contain *Salmonella*; *internal check samples within the Atria company every 2 months*)
2. What species/strains are used? *S. dublin* SLV – 242, *bovismorbific*, and *enteritidis* has been used, among others
3. How many samples are analyzed and how often?. See answer to question 1 (in this section)
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing?. Yes
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts?. "approximately 4 bacteria / ml of reconstituted sample"

#### Methodology for HACCP generic *E. coli* samples (in-plant or other private labs)

Does this lab analyze HACCP generic *E. coli* samples? Yes

How are HACCP *E. coli* samples received & recorded? The lab is in the establishment

Are HACCP *E. coli* samples analyzed on the day of receipt? Yes

What method is used for HACCP generic *E. coli* samples? NMKL 147:1993

Is it a quantitative method? Yes

What buffer (and what volume) is used for:

*E. coli* sponge samples? Same as for *Salmonella*

Poultry rinsates for generic *E. coli*? N/A

What analytical controls are used? *E. coli*, lot # 335201, Cat # 0335P, Expiration June '02, from Microbiologics, St. Cloud, MN 56303

Are they employed for each sample set? Yes

How are HACCP *E. coli* results calculated and/or expressed? Detected / not detected

How are *E. coli* results recorded: Graph form

Data sheets/work sheets?

Log books?

How and to whom are HACCP *E. coli* results reported? Both to the IIC and the management

Are "check" samples periodically used to test the proficiency of the lab and analysts for generic *E. coli* testing?

1. For individual analysts or for the lab as a whole? Lab as a whole; the analyst participates. Provided by the Swedish National Food Administration, four times annually (but the check samples do not always contain *Salmonella*; internal check samples within the Atria company every 2 months
2. What species/strains are used? *E. coli* SLV – 082
3. How many samples are analyzed and how often? See answer to Question 1, this section
4. Are both inoculated and uninoculated samples provided to analysts for the proficiency testing? Yes
5. How many colony-forming units (cfu) per gram are inoculated into the proficiency samples provided to analysts? Log 4.1 cfu/ml